K113365

MAR 2 9 2012

Attachment B

510(k) Summary

1.	Manufacturer:	Advanced Imaging Research, Inc. 4700 Lakeside Avenue, Suite 400 (Physical Location) Cleveland, OHIO 44114 PO Box 603220 **(Use for Correspondence)** Cleveland, OHIO 44103 1262 E 49th Street, Suite 400 (Courier Address) Cleveland, OHIO 44114 Phone: 216-426-1461 Fax: 216-426-1180
2.	Registration Number:	3004036149
3.	Contact:	Ravi Srinivasan, President Phone: 216-426-1461 Fax: 216-426-1180 email: ravi@sreemedical.com
4.	Device Name:	Magnetic Resonance Diagnostic Device
	Proprietary Name:	Infant Array
5.	Type of Submission:	Traditional
6.	Classification of Device:	21CFR 892.1000
	Class of Device:	Class II
	Product Code:	90 MOS (Magnetic Resonance Specialty Coil)
7.	Intended Use:	The Infant Array is a receive-only RF coil, used for obtaining high resolution images and spectra of the infant brain, spine, heart, torso and extremity in GE, Siemens and Philips 1.5T and 3.0T magnetic resonance imaging systems and magnetic resonance compatible incubators. Indications for use are same as that for standard MR imaging and spectroscopy.
8.	Device Description:	The Infant Array is a 20-element receive-only radio-frequency (RF) coil array well suited for routine and parallel imaging. The Infant Array (IA) consists of an Infant Head Spine Array (IHSA) and an anterior Cardiac section (CAR). The IHSA can be used alone for spine and

		brain examinations or in conjunction with the anterior cardiac section necessary for cardiac and torso MRI exams. The anterior cardiac section cannot be used alone. This anterior cardiac section is supported on a sliding adjustable height gantry. Coil elements and associated circuitry are enclosed in a rigid former to prevent any exposure to patient or environment. The plastic materials used are fire rated and have a high impact and tensile strength. The coil design facilitates scanning of low birth weight pre-term babies, term newborns and small infants with different body sizes and maximizes comfort and ease of use.
9.	Marketed Device:	Infant Head Spine Array, Infant Array for GE, Siemens, Philips 1.5T and 3.0T MRI Scanners
10.	Comparison to Predicate:	1.5T 16 Channel GE Brain Spine Array (K052621) 3.0T 16 Channel GE Head Neck Spine Array (K093348)

In general, the Infant Array is similar in use to the above-mentioned adult sized head neck spine arrays and is considered a scaled-down version that is receive-only and well suited for parallel imaging as follows:

Intended use	Proton 1H 1D, 2D, 3D T1, T2 weighting, proton density, chemical shift, diffusion weighted imaging, angiography, functional MRI, chemical shift imaging, spectroscopy
Indications for Use	The Infant Array when used in conjunction with GE, Siemens and Philips 1.5T and 3T MRI systems *or* Infant Array when used with the MRI compatible incubator and in conjunction with the abovementioned MRI systems provide imaging of the infant's brain, spine, heart, torso and extremities. When interpreted by a trained physician, these images provide information that can be useful in the determination of the diagnosis.
Coil Enclosure Material	Polycarbonate, polyurethane plastic. The plastic materials used are fire rated and have a high impact and tensile strength similar to Advanced Imaging Research's Neonate Coils (K023929, K083541) and infant cardiac array (K083539)
Coil Design	20 element, receive-only RF coil array. The Infant Array consists of two sections: infant head spine array (IHSA) and anterior cardiac section (CAR), which is positioned above the IHSA and supported on a sliding adjustable height gantry. Coil elements and associated circuitry are

	enclosed in a rigid former to prevent any exposure to patient or environment.
Decoupling	With RF chokes and fast acting pin-diode switching diodes similar to GE's 1.5T and 3.0T 16 channel head neck spine arrays (K052621, K093348).
Prevention of RF Burns	Does not transmit RF power, decoupling isolates the coil elements from RF fields during RF transmission similar to GE's 1.5T and 3.0T 16 channel head neck spine arrays (K052621, K093348). Coil elements and associated circuitry are enclosed in a non-conductive plastic housing.
Radio-Frequency Absorption	Coil is receive-only and does not transmit RF power, similar to GE's 1.5T and 3.0T 16 channel head neck spine arrays (K052621, K093348).
Formation of Resonance Loops	Active diodes and RF fuses isolate the coil elements from whole body RF coil transmit; length and routing of output cable does not permit looping similar to similar to GE's 1.5T and 3.0T 16 channel head neck spine arrays (K052621, K093348).
11. Summary of Studies:	Testing was performed to demonstrate that the Infant Array meet the predetermined acceptance criteria

Conclusion:

It is the opinion of Advanced Imaging Research that the Infant Array herein is substantially equivalent to GE's adult head and neck spine arrays. Testing and usage of the Infant Array does not result in any new potential hazards.

12. List of Attachments

1. 510(k) Summary
2. Statement of Indications
3. Device Characteristics: Drawings/Illustrations
4. Device Characteristics: Imaging Performance
5. Safety
6. Labeling – Product Brochures, Operator's Manuals
7. Comparison to Predicate Device
8. Images
9. Publications
10. Form 3654, Form 3674

We believe this narrative, the foregoing information, and the referenced attachments demonstrate the substantial equivalence of the Infant Array to the predicate devices, and will be sufficient for the Food and Drug Administration to reach a favorable decision on this submission.

I certify that, in my capacity as the Official Correspondent for Advanced Imaging Research Inc., I believe that, to the best of my knowledge, all data and information submitted in this pre-market notification are truthful and accurate and that no material fact has been omitted. I can be reached at the following, if necessary. Thank you for your consideration of this submission.

Contact Information: Phone: 216-426-1461 Fax: 216-426-1180 email: ravi@sreemedical.com

Respectfully Submitted,

Ravi Srinivasan, President

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

MAR 29 2012

Mr. Ravi Srinivasan
President
Advanced Imaging Research, Inc.
P.O. Box 603220
CLEVELAND OH 44103

Re: K113365
Trade/Device Name: Infant Array
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: 90 MOS
Dated: February 22, 2012
Received: February 28, 2012

Dear Mr. Srinivasan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

510(k) Number (if Known): K113365

Device Name: Infant Array

Indications for Use:

The Infant Array when used in conjunction with GE, Siemens and Philips 1.5T and 3T MRI systems *or* Infant Array when used with the MRI compatible incubator and in conjunction with the abovementioned MRI systems provide imaging of the infant's brain, spine, heart, torso and extremities. When interpreted by a trained physician, these images provide information that can be useful in the determination of the diagnosis.

- Anatomical Region: Pre-, term newborn infant heart and torso
- Nucleus Excited: Proton 1H
- Diagnostic Uses: 1D, 2D, 3D T1, T2 Weighting
  Proton Density
  Chemical Shift
  Diffusion Weighted Imaging
  Functional MRI
  MR Blood Flow (angiography)
  MR Spectroscopy

(PLEASE DO WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-the-Counter Use _____
(Per 21 CFR 801-109)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
510K K113365

(Optional Format 1-2-96)